



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,702	03/29/2004	Makoto Ootsuka	Q80196	1819
23373	7590	12/19/2007		
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER SASAN, ARADHANA	
			ART UNIT	PAPER NUMBER
			1615	
			MAIL DATE	DELIVERY MODE
			12/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/810,702	OOTSUKA ET AL.	
	Examiner	Art Unit	
	Aradhana Sasan	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 7-11, 13-18 and 22-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 12, 19-21 and 30-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I (claims 1-21 and 30-36), drawn to a cured porous calcium phosphate material comprising a drug in the reply filed on August 24, 2007 is acknowledged.
2. Applicant's election of "protein bone growth factor" as the elected species in the reply filed on November 14, 2007 is acknowledged.
3. Applicant did not elect a single disclosed species of drug other than a protein bone growth factor, therefore claims 7-11 and 13-18 are withdrawn from consideration because they are drawn to non-elected species.
4. Claims 22-29 are withdrawn from consideration as they are drawn to a non-elected invention.
5. Claims 1-6, 12, 19-21 and 30-36 are included in the prosecution.

Priority

6. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on July 31, 2003. It is noted, however, that applicant has not filed a certified copy of the 2003-283968 application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1615

8. Claims 1-2 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Barralet et al. (Biomaterials 23 (2002) 3063-3072).

The claimed invention is a cured porous calcium phosphate material comprising at least one penetration pore, where the pore has a diameter of 70 μ m to 4mm and the material has a porosity of 20% to 80%.

Barralet discloses the preparation of macroporous calcium phosphate cement (CPC) tissue engineering scaffold (Abstract). Table 2 discloses the measured total porosity ranging from 31% to 62% (Page 3065). The pore size distribution of the CPC specimens is in the range of 350 μ m -6nm (Page 3065).

Regarding instant claim 1, the limitations are anticipated by the teaching of Barralet because a macroporous calcium phosphate material with porosity ranging from 31 to 62% and a pore size distribution of 350 μ m -6nm is taught (Page 3065).

Regarding instant claim 2, the limitation of the pores arranged in a three-dimensional network structure are anticipated by Figures 1 and 2 which show a three-dimensional network of pores in the CPC (Figures 1 and 2).

Regarding instant claim 32, the limitation of the tissue engineering scaffold is anticipated by the preparation of macroporous calcium phosphate cement (CPC) tissue engineering scaffold as disclosed by Barralet (Abstract).

Therefore, the limitations of claims 1 and 2 are anticipated by the teachings of Barralet.

Claim Rejections - 35 USC § 103

Art Unit: 1615

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-3, 5 and 19-21 and 30-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jessen (US 5,916,510) in view of Miao et al. (Materials Letters 58 (2004) available online July 17, 2003, 397-402).

Jessen discloses a ceramic structure with a porosity of 10-80% and with elongated and parallel channels (Abstract). The porous ceramic structure "can be used at high temperatures exceeding 1000°C (Col. 2, lines 20-21). The ceramic structures "can be used in medical applications, such as bone repair where the continuous channels permit bone growth elements to enter the channels and produce a strong bond between a living bone and the channeled ceramic structure" (Col. 2, lines 29-32). Figure 1 shows the channels "as being spaced, elongated and parallel to each other although it is possible to orient them in any direction desired, such as vertically, perpendicularly, at an angle, or a combination thereof" (Col. 2, lines 43-47). Specialty ceramics such as hydroxyapatite are disclosed (Col. 3, lines 10-16). The ceramic structure is calcined or heat treated in the temperature range of 500-700°C (Col. 4, lines 57-59).

Jessen does not expressly teach the pore diameter of the ceramic structure.

Miao discloses porous calcium phosphate ceramics with "high porosity, high pore interconnectivity and controlled pore size" (Abstract). The role of porous calcium

Art Unit: 1615

phosphate ceramics "in treating bone problems with the ... tissue engineering approach, as it involves loading proper cells into porous ceramics (scaffolds) and implanting the cell-loaded scaffolds into a host body for achieving bone tissue regeneration" (Page 397). "By coating the porous calcium phosphate ceramics with the calcium phosphate cement, the porous calcium phosphate ceramics maintained the capability of incorporation of drugs or proteins" (Page 398). Figure 5 shows the "macropores (about 1mm in pore size) and the high pore interconnectivity of the highly porous hydroxyapatite ceramic body" (Page 400, Figure 5). "Another strengthening method would be the infiltration of some bioactive polymer such as PolyactiveTM or some biodegradable polymer such as PLGA (poly(lactic-co-glycolic acid)) into the micropores within the struts" (Page 401).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a ceramic structure with 10-80% porosity that can be used in medical applications, such as bone repair, as suggested by Jessen, combine it with the porous calcium phosphate ceramics with macropores (about 1mm in pore size), as suggested with Miao, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Miao teaches that "by controlling the porosity and pore size, the highly porous ceramics would have a compressive strength comparable to the compressive strengths of cancellous bones (2-12 MPa)" (Page 401).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed

Art Unit: 1615

invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claim 1, the limitation of a cured porous calcium phosphate material would have been obvious to one skilled in the art over the porous ceramic structure, as taught by Jessen (Col. 2, lines 20-21) and the porous calcium phosphate ceramics taught by Miao (Abstract). The limitation of the pore diameter of 70 μ m to 4mm would have been obvious over the macropores (about 1mm in pore size) taught by Miao (Page 400, Figure 5). The limitation of the porosity of 20% to 80% would have been obvious over the porosity of 10-80% of the ceramic structure as taught by Jessen (Abstract). The high porosity is depicted by Miao because Figure 5 contains 12 visible pores which a skilled artisan would consider a high percentage of pores per unit area of the ceramic material (Figure 5).

Regarding instant claim 2, the limitation of a plurality of penetration pores arranged in a three-dimensional network structure would have been obvious to one skilled in the art over the orientation of channels in the ceramic structure that can be parallel or oriented in any direction desired, such as vertically, perpendicularly, or at an angle as taught by Jessen (Col. 2, lines 43-47).

Regarding instant claim 3, the limitation of a biocompatible polymer would have been obvious over the teaching by Miao that a bioactive polymer such as PolyactiveTM or some biodegradable polymer such as PLGA (poly(lactic-co-glycolic acid)) can be used for strengthening the highly porous ceramic structure (Page 401).

Regarding instant claim 5, the limitation of a drug would have been obvious over the porous calcium phosphate ceramics with the capability of incorporation of drugs or proteins as taught by Miao (Page 398).

Regarding instant claims 19-20, the limitation of the low-temperature curable material would have been obvious over the ceramic structure that is calcined or heat treated in the temperature range of 500-700°C, as taught by Jessen (Col. 4, lines 57-59).

Regarding instant claim 21, the cross-sectional shape of the penetration pore would have been obvious over the round cross-sectional shape of the penetration pores taught by Jessen (Figure 1).

Regarding instant claim 30, the limitation of a biomaterial comprising the material according to claim 1 would have been obvious over the use of the ceramic structures in medical applications, such as bone repair, as taught by Jessen (Col. 2, lines 29-32).

Regarding instant claim 31, the drug controlled release body would have been obvious over the porous calcium phosphate ceramics with the capability of incorporation of drugs or proteins as taught by Miao (Page 398). One skilled in the art would know that the ceramic will release the drug in a controlled or sustained manner and that the release will not be an immediate release.

Regarding instant claim 32, the tissue engineering scaffold would have been obvious over the role of porous calcium phosphate ceramics, taught by Miao, "in treating bone problems with the ... tissue engineering approach, as it involves loading

Art Unit: 1615

proper cells into porous ceramics (scaffolds) and implanting the cell-loaded scaffolds into a host body for achieving bone tissue regeneration" (Page 397).

Regarding instant claims 33-36, the limitation of the material according to claim 1 comprising a plurality of coplanar penetration pores would have been obvious over the teaching by Jessen that the channels (which read on the instant penetration pores) can be spaced elongated and parallel to each other although it is possible to orient them in any direction desired, such as vertically, perpendicularly, at an angle, or a combination thereof (Col. 2, lines 43-47).

11. Claims 4, 6 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jessen (US 5,916,510) in view of Miao et al. (Materials Letters 58 (2004) available online July 17, 2003, 397-402) and further in view of Kwan (US 2001/0014830).

The teachings of Jessen and Miao with respect to the porous calcium phosphate structure are stated above.

Jessen and Miao do not expressly teach a biocompatible polymer with the porous calcium phosphate material.

Kwan discloses a bone grafting matrix "which is porous and maintains structural integrity and porosity after implant for a period sufficient to augment the bone replacement process. The matrix comprises mineralized fibrillar insoluble collagen, collagen derivative or modified gelatin ... the minerals comprise particulate calcium phosphate ..." (Page 1, [0014]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a ceramic structure with 10-80% porosity that can be used

Art Unit: 1615

for bone repair, as suggested by Jessen, combine it with the porous calcium phosphate ceramics with macropores (about 1mm in pore size), as suggested with Miao, and further combine it with a bone grafting matrix comprising biocompatible polymers collagen (or gelatin) and calcium phosphate, as suggested by Kwan, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Kwan teaches that “the matrix may be used as a grafting material and/or a delivery vehicle for osteogenic growth factor. The matrix may be mixed with autogenous bone marrow and implanted for bone regeneration” (Page 1, [0014]).

Regarding instant claim 4, the limitation of the biocompatible polymers would have been obvious over the bone grafting matrix comprising biocompatible polymers collagen (or gelatin) and calcium phosphate, as taught by Kwan (Page 1, [0014]).

Regarding instant claim 6, the limitation of the drug would have been obvious over the porous calcium phosphate ceramics with the capability of incorporation of drugs or proteins as taught by Miao (Page 398) and the teaching by Kwan that the matrix may be used as a “delivery vehicle for osteogenic growth factor” (Page 1, [0014]).

Regarding instant claim 12, the limitation of the protein bone growth factor would have been obvious over the osteoinductive bone growth factors, BMP'S (bone morphogenetic proteins), calcitonin or other growth factors that augment bone growth, as taught by Kwan (Page 3, [0038]).


Art Unit: 1615

Conclusion

12. No claims are allowed.
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600